IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	C. Kost et al.	Attorney Docket No.:	MMSI121562
Application No.:	10/674,904	Group Art Unit:	3622
Filed:	September 30, 2003	Examiner:	--
Title:	DRUG SAMPLE FULFILLMENT ARCHITECTURE		

TRANSMITTAL LETTER FOR PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102 AND M.P.E.P. § 708.02(viii)

Seattle, Washington 98101

April 15, 2004

TO THE COMMISSIONER FOR PATENTS:

A. Transmitted herewith is a Petition to Make Special in the above-identified application, including five enclosures as listed in the Petition.

B. Also enclosed is check No. 154988 in the amount of $130.00 to cover the petition fee.

C. Fee Charges or Credit for Overpayment

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.18 which may be required during the entire pendency of the application, or credit any overpayment, to Deposit Account No. 03-1740. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application. A copy of this document is enclosed.

Respectfully submitted,

CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC

Jerald E. Nagae
Registration No. 29,418
Direct Dial No. 206.695.1705

I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first class mail with postage thereon fully prepaid and addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the below date.

Date: April 15, 2004 Hilda J. delGraaff

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AND M.P.E.P. § 708.02(viii)

Seattle, Washington 98101

April 15, 2004

TO THE COMMISSIONER FOR PATENTS:

Applicants respectfully petition that the above-identified patent application be made special and considered for accelerated examination, and in support thereof submit the following:

A. The present petition to make special is accompanied by the fee set forth in 37 C.F.R. § 1.17(h), in the amount of $130.

B. All the claims in the application are directed to a single invention, for if the Office determines that all the claims presented are not directed to a single invention, applicants will make an election without traverse as a prerequisite to the grant of special status.

C. A pre-examination search was conducted in the U.S. Patent and Trademark Office. The search was conducted in Class 705 (Data Processing: Financial, Business Practice, Management, or Cost/Price Determination), subclasses: 1 (Automated Electrical Financial or Business Practice or Management Arrangement), 2 (Health care management; e.g., record management, ICDA billing); 3 (Patient record management); 5 (Reservation, check-in, or booking display for reserved space); 6 (Coordination of plural reservations; e.g., plural trip segments; transportation and accommodation, etc.); 7 (Operations research); and 8 (Allocating resources or scheduling for an administrative function).

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The patents and applications located in the search are listed below:

Patentee/Applicant	U.S. Patent No./Application No.
*Thornton	5,628,530
*Cunningham	5,832,449
*Cunningham	6,055,507
Lester et al.	6,021,392
Williams et al.	6,315,720 B1
Lupi	6,012,740
Hamby et al.	6,135,507
Feeney, Jr. et al	US 2002/0032582 A1
*Adams	US 2002/0055856 A1
Pham et al.	US 2002/0065683 A1
Enos et al.	US 2002/0138303 A1
*Subich	US 2002/0161607 A1
Marasco	US 2002/0173990 A1

D. Copies of those patents marked with an asterisk (*) above are enclosed. A discussion of these references is set forth below which points out, with the particularity required by 37 C.F.R. § 1.111(b) and (c), how the claimed subject matter is patentable over these references. Prior to this discussion, a brief summary of the present invention is presented. It should be understood that the following summary is provided only to assist the Examiner's understanding of the present invention in consideration of the present petition, and is not intended to limit the scope of the claims of the present application.

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Summary of the Present Invention

One aspect of the present invention is to deliver sample pharmaceutical drugs to physicians in several different manners using a drug fulfillment platform. Traditionally, sales representatives for pharmaceutical companies visit a physician at his/her office and provide information about and samples of new drugs. The physician stores the samples at his/her office and then provides the samples to patients as appropriate. One drawback of providing such samples is that the pharmaceutical company has no way of correlating samples given to a specific physician with the extent to which that physician prescribes the drug.

The FDA has implemented rules with respect to providing drug samples, including accountability as to whom the drug samples are given, where the samples are stored, and the status of the samples. These rules were intended to make sure that samples were properly utilized and not diverted for unintended purposes, and also to make sure that the samples are properly stored and do not become too old so as to lose their efficacy.

The present invention addresses the shortcomings of past sample distribution methods, including the concerns of the FDA. Under the present invention, a drug fulfillment platform is provided so a physician can order actual drug samples on-line or can order coupons for drug samples on-line to be given to patients who in turn go to a pharmacy to obtain the free samples. As a third alternative, the physician can print the coupons at his/her own office to give to patients who in turn redeem the coupons at a pharmacy. The coupons that are printed by the physician are dynamically built at the time requested so as to include the physician's information, the particular drug requested, its manufacturer, the strength of the drug, the expiration date of the voucher, and the physician's DEA number. Through this process, certain information is captured, including the name and address of the physician, the date of the redemption of the coupon, the identity of the drug sample given, as well as certain information about the patient,

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but without identifying the patient. This can be made available to the pharmaceutical company so that the samples actually given to patients can be tracked. The pharmaceutical company can also obtain information as to the prescription of the drug in question by a physician through an information collection system. In this manner, the drug company can evaluate the effectiveness of providing sample drugs to a physician. This enables the pharmaceutical company to make determinations, including the success of their sample program.

Pharmaceutical companies have certain brand rules that they use in determining what physician is to be given sample drugs in general, as well as what sample drugs are to be made available, and the quantity of such sample drugs. These brand rules are established on a physician-by-physician basis and are in effect when a physician requests sample drugs. Such rules can be based on many factors, including the specialty of the physician, the physician's location, the physician's age, the physician's past history of requesting sample drugs and providing such samples to patients, as well as the physician's history in prescribing such drugs. The present invention provides a drug and sample fulfillment platform for implementing the applicable brand rules without the use of a sales representative.

The present invention can also take into consideration preferences of a physician, including whether the physician prefers actual sample drugs, printed coupons, or desires to print coupons at his/her own office. Preferences also may include whether the physician can or will accept calls by pharmaceutical reps and, if so, which day of the week and perhaps even what time of day. A one-to-one relationship can be established between the pharmaceutical company and the physician with respect to the providing of drug samples, and such relationship can be adjusted over time.

As another aspect of the present invention, when a physician desires to obtain sample medication and thus logs on to a Web site, all of the sample drugs that the physician is permitted

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to order can be listed. The sample drugs may be from a number of different pharmaceutical companies. This eliminates the need for a physician to have to go to a specific pharmaceutical company's drug site to order a particular drug sample, which would be very time consuming and cumbersome.

Also, according to the drug fulfillment platform of the present invention, a link to a Web site for sample ordering and other services would be available at popular physicians' Web portals, as well as a desktop icon associated with software commonly used by physicians in their day-to-day office functions. Thus, it would be easy for a physician to reach the Web site to seek the services desired.

The present invention can also serve as an avenue for consumers to learn about available drugs and request samples. Consumers can access a Web site and ask for a sample of a drug. This request is forwarded to a pharmaceutical company who, in turn, refers the request to a physician in the locale of the consumer. The consumer is advised as to the particular physician or physicians from whom the sample drug can be requested.

Discussion of Relevant References Identified

Thornton, U.S. Patent No. 5,628,530, discloses a system for tracking starter drug samples provided to patients by their physicians. The samples are dispensed to patients using a multiple part, drug-specific voucher, such as a "smart card" or a pre-printed two-part voucher, see Figures 4 and 5. The voucher has the marketing information portion and a separable prescription portion that is to be filled in by the prescribing physician. The physician specifies the quantity of the drug and dosage, as well as patient demographic information and basic physician information. The prescription portion is separated from the marketing information portion at the dispensing pharmacy, and then the prescription information is electronically stored in the

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pharmacy computer. From that location the information is electronically transmitted to a central computer, for instance, a pharma. See the flow chart of Figure 1.

Cunningham, U.S. Patent Nos. 5,832,449 and 6,055,507, disclose a system that tracks drug samples by linking prescribers and pharmacies to a central computer. Product trial media (which can be a card with a magnetic information strip), may be used for tracking purposes. The sample drug product media (magnetic cards) are distributed to prescribers for subsequent passing out to patients. The patients in turn exchange the media for actual pharmaceutical samples at a pharmacy. The media are magnetically encoded with information that identifies a particular trial drug. The media must first be activated via the central computer station by a participating medical physician or prescriber before the media is given to the patient. Later, before filling the pharmaceutical sample prescription identified by the media, the pharmacy must validate the media via a link with the central computer station. Then the pharmacy dispenses the trial drug. The central computing station may include a database that records information related to use of the media so that pharmaceutical samples can be tracked.

Adams, U.S. Patent Application Publication No. 2002/0055856, discloses a system to deliver sample drugs to patients. The pharma provides physicians with tokens which are given to patients for redemption at a pharmacy. The tokens may be in the form of a partially completed script. See, for example, Figures 2a and 2b of the patent application. However, before the physician can provide a token to a patient, the token has to be adjudicated by a claim adjudication system. Information in this regard is collected and forwarded to the pharmas. As another aspect of the disclosed invention, drug utilization review may be provided by the claim adjudication system.

Subich, U.S. Patent Application Pub. No. 2002/0161607, pertains to a system to track and control the distribution of drug samples. Indicia on the drug samples are electronically read

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when the samples are provided to patients. The locally-gathered distribution information is then provided to a central database for processing. In accordance with the Subich method, all pharmaceutical drug samples are tracked at a given dispensing location. An indicia reader at the dispensing location is used to read the pharmaceutical drug sample indicia into a dispensing location database upon receipt of the samples; then again later, upon dispensing of the samples. This method is said to enable the Pharma to quickly and easily ascertain inventory levels of pharmaceutical drug samples at a given dispensing location, including expiration dates of the samples. The Pharma can communicate with the dispensing location via the Internet without actually having to visit the dispensing locations.

Discussion of References

The claims of the present application are directed to systems and methods for using the drug fulfillment platform of the present invention to accomplish drug sample distribution by enabling prescribers to order sample drug or vouchers for sample drugs on-line, or by enabling prescribers to print vouchers or coupons for drug samples at his/her own office.

Independent Claim 1 of the present application specifies that the drug fulfillment platform of the present invention implements brand rules for guiding the distribution of drug samples without the need for a sales representative.

Independent Claim 6 of the present application specifies that Web pages are coupled to the drug sample fulfillment platform to which a prescriber connects to order sample drugs.

Independent Claim 11 specifies a method of marketing pharmaceutical drugs using a Pharma rules sample engine for performing personalized and intelligent brand rule implementation and a marketing sample engine with drug sample suppliers and Web portal for prescribers.

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Independent Claim 16 is directed to the drug fulfillment platform itself, specifying that the platform includes a drug sample Web site for mating to a portal, and a request database for receiving requests of a prescriber to the Web site for drug samples via a request database. The request database permits the prescriber to print coupons or print an order for physical samples or pads of pre-printed vouchers.

Independent Claim 21 specifies a network system for ordering pharmaceutical sample drugs comprising a drug sample fulfillment platform that in turn comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink. Further, the drug sample Web site presents a Web page that includes selectable options for the prescriber to order drug samples.

Independent Claim 31 specifies a method for accessing a drug sample fulfillment platform, and Independent Claim 46 specifies a method for creating a stream of revenue from a drug sample distribution which includes capturing a sample request on a drug sample fulfillment platform and charging the pharmaceutical company a transaction fee for drug samples requested by the platform.

None of the above-noted prior patents and patent applications teach or suggest the drug sample fulfillment platform of the present invention. All of the patents and patent applications noted above focus on tracking drug samples that are provided to patients by physicians. It is still necessary for the physicians to obtain the drug samples or vouchers or tokens for drug samples from a sales representative. For example, in Thornton, a smart card or pre-printed two-part voucher must be delivered to the physician, who in turn provides the voucher to patients. In Cunningham, magnetic cards are distributed to prescribers for subsequent passing out to patients. These cards are used to track distribution of drug samples. In Adams, pharmaceutical companies, or their representatives, provide physicians with physical tokens that are given to

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patients for redemption at a pharmacy. In Subich, when drug samples are provided to patients, indicia on the drug samples are electronically read. This information is sent to a central database for processing.

Based on the foregoing, applicants believe that all of the claims of the present application are allowable over Thornton, Cunningham, Adams, and Subich.

Applicants respectfully request the granting of this petition and an early examination on the merits of the present application.

Respectfully submitted,

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Date: April 15, 2004 Hilda J. deGraff

Enclosures:

Thornton, U.S. Patent No. 5,628,530
Cunningham, U.S. Patent Nos. 5,832,449 and 6,055,507
Adams, U.S. Patent Application Publication No. 2002/0055856
Subich, U.S. Patent Application Publication No. 2002/0161607

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